

**Remarks/Arguments**

Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 are pending. Claims 1-49, 53, 55, 76, 78, 96 and 105-107 remain canceled. No claims have been amended and therefore no new matter has been added

**103 Rejections**

Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 remain rejected under 35 U.S.C. §103(a) as being unpatentable over WO 98/07414 (“the ‘414 publication”) in view of US Patent No. 5,976,577 (“Green”) or US Patent No. 6,475,510 (“Venkatesh”). The Examiner indicated that the ‘414 publication discloses the same process of preparing rapidly dispersing oral dosage forms of hydrophobic compounds as the instant application but does not disclose the additional step of adding at least two rapidly dispersible matrix-forming releasing agents. The Examiner further indicated that both Green and Venkatesh disclose fast dispersing solid dosage forms of various drugs. Applicants disagree.

Applicants submit, herewith, a Declaration by Indu Parikh under 37 CFR § 1.132 who is an inventor of the instant application and the ‘414 publication. Further, Indu Parikh establishes that the ‘414 publication does not describe an invention that was known or used by others before invention by applicants under 35 U.S.C. § 103(a). Further, he states that any invention disclosed but not claimed in the ‘414 publication was derived from his work. Thus, the ‘414 publication, insofar as its teachings relate to the subject matter of the instant claims, is not a publication by another, and thus cannot be prior art under 35 U.S.C. § 102(a) or under 35 U.S.C. § 103(a). Further, the ‘414 application cannot be prior art under 35 U.S.C. 102(b) because it was published within one year of the effective filing date of the instant application.

Withdrawal of the rejection is thus respectfully requested.

### **Double Patenting**

Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 remain rejected under obviousness-type double patenting over claims 1-11 of U.S. Patent No. 5,922,355 ("Parikh I"). Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 remain rejected under the obviousness-type double patenting over claims 1-5 of U.S. Patent No. 6,228,399 ("Parikh II"). Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 remain rejected under obviousness-type double patenting over claims 1-22 of U.S. Patent No. 6,465,016 ("Parikh III").

Applicants submit that claims 1-11 of Parikh I do not teach or suggest the limitations of claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 in light of the general knowledge of one of ordinary skill in the art and that there has not been sufficient explanation pertaining to why despite these the instant claims are obvious over claims 1-11 of Parikh I.

Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.<sup>1</sup>

Pending claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 recite a process for the preparation of a rapidly disintegrating solid dosage form capable of forming a stable suspension without irreversible particle aggregation, particle agglomeration, or particle growth, wherein the concentration of the phospholipid in the aqueous suspension ranges from about 0.1% w/w to about 90% w/w; and wherein the mean volume weighted particle size of the water-insoluble or poorly water-soluble drug particles in the suspension ranges between about 0.05 and about 10 micrometers. Further, the suspension does not have more than about 20% by weight of particle aggregation or agglomeration compared with the amount of aggregation or agglomeration of particles comprising a pre-dried suspension. Moreover, the support matrix dissolves or substantially disperses in a rapid disintegration time of less than 2 minutes upon contact between the solid and aqueous environment resulting in a release of the surface stabilized drug particles into the aqueous environment as a suspension and after contact between the solid and the aqueous

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<sup>1</sup> MPEP § 2141

environment, the resulting suspension comprises no more than about 20% by weight of aggregated or agglomerated primary particles. The introduction of the claimed matrix-forming agent(s) in the claimed invention, which must dissolve or disperse upon contact with an aqueous environment, serves to stabilize the phospholipid coated drug particle during the freeze-drying process and in the freeze-dried product by suppressing any tendency of particle agglomeration or particle growth. Further, the rapid disintegration time of less than 2 minutes allows the active ingredient to be available for absorption.

Claims 1-11 of Parikh I do not teach or suggest a process for the preparation of a rapidly disintegrating solid dosage form comprising a concentration of the phospholipid in the aqueous suspension ranges from about 0.1% w/w to about 90% w/w, with a mean volume weighted particle size of the water-insoluble or poorly water-soluble drug particles in the suspension that ranges between about 0.05 and about 10 micrometers. Nor do claims 1-11 of Parikh I teach or suggest a solid dosage form with at least two rapidly dispersible matrix-forming agents said at least two rapidly dispersible matrix-forming agents, being present in an amount of between 0.1% w/w and 90% w/w of the aqueous suspension wherein upon reconstitution in an aqueous environment, the suspension has no more than about 20% by weight of particle aggregation or agglomeration compared with the amount of aggregation or agglomeration of particles comprising a pre-dried suspension. Moreover, claims 1-11 of Parikh I do not encompass a process for the preparation of a rapidly disintegrating solid dosage form having surface stabilized drug particles dispersed and embedded throughout a support matrix formed by the at least two matrix-forming bulking/releasing agents, or combination thereof, wherein the support matrix dissolves or substantially disperses in a rapid disintegration time of less than 2 minutes upon contact between the solid and aqueous environment resulting in a release of the surface stabilized drug particles into the aqueous environment as a suspension; and further wherein, after contact between the solid and the aqueous environment, the resulting suspension comprises no more than about 20% by weight of aggregated or agglomerated primary particles.

Applicants submit that claims 1-11 of Parikh I do not teach or suggest all of the limitations of pending claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 and that the Examiner has not explained why that despite these differences the instant claims are obvious over claims 1-11 of Parikh I. Thus, Applicants submit that claims 50-52, 54, 56-75, 77, 79-95,

97-104 and 108-131 are not obvious over the teachings of Parikh I and respectfully request that this rejection be withdrawn.

Applicants submit that claims 1-5 of Parikh II do not teach or suggest the limitations of claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 in light of the general knowledge of one of ordinary skill in the art and that there has not been sufficient explanation pertaining to why despite these the instant claims are obvious over claims 1-11 of Parikh II.

As articulated above, prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.

As articulated above, Applicants submit that the teaching of pending claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 are as indicated above, however, importantly, the phospholipid in the aqueous suspension ranges from about 0.1% w/w to about 90% w/w; the mean volume weighted particle size of the water-insoluble or poorly water-soluble drug particles in the suspension ranges between about 0.05 and about 10 micrometers; the suspension does not have more than about 20% by weight of particle aggregation or agglomeration compared with the amount of aggregation or agglomeration of particles comprising a pre-dried suspension. Additionally, the support matrix dissolves or substantially disperses in a rapid disintegration time of less than 2 minutes upon contact between the solid and aqueous environment resulting in a release of the surface stabilized drug particles into the aqueous environment as a suspension and after contact between the solid and the aqueous environment, the resulting suspension comprises no more than about 20% by weight of aggregated or agglomerated primary particles.

Claims 1-5 of Parikh II do not teach or suggest a process for the preparation of a rapidly disintegrating solid dosage form comprising a phospholipid in the aqueous suspension that ranges from about 0.1% w/w to about 90% w/w, with a mean volume weighted particle size of the water-insoluble or poorly water-soluble drug particles in the suspension between 0.05 and 10 micrometers. Further, claims 1-5 of Parikh II do not teach a process for the preparation of

rapidly disintegrating solid dosage form with at least two rapidly dispersible matrix-forming agents being present in an amount of between 0.1% w/w and 90% w/w of the aqueous suspension wherein upon reconstitution in an aqueous environment, the suspension has no more than about 20% by weight of particle aggregation or agglomeration compared with the amount of aggregation or agglomeration of particles comprising a pre-dried suspension. Moreover, claims 1-5 of Parikh II do not encompass a process for the preparation of rapidly disintegrating solid dosage form with a support matrix that dissolves or disperses in a rapid disintegration time of less than 2 minutes upon contact between the solid and aqueous environment resulting in a release of the surface stabilized drug particles into the aqueous environment as a suspension.

For the above reasons, Applicants submit that claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 are not obvious over the teachings of claims 1-5 of Parikh II and respectfully request that this rejection be withdrawn.

Applicants submit that claims 1-22 of Parikh III do not teach or suggest the limitations of claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 in light of the general knowledge of one of ordinary skill in the art and that there has not been sufficient explanation pertaining to why despite these the instant claims are obvious over claims 1-11 of Parikh III.

As articulated above, prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.

Applicants submit that the teaching of pending claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 are as indicated above, including the phospholipid is in the aqueous suspension from about 0.1% w/w to about 90% w/w; the mean volume weighted particle size of the water-insoluble or poorly water-soluble drug particles in the suspension ranges between about 0.05 and about 10 micrometers; the suspension does not have more than about 20% by weight of particle aggregation or agglomeration compared with the amount of aggregation or agglomeration of particles comprising a pre-dried suspension. Moreover, the support matrix dissolves or substantially disperses in a rapid disintegration time of less than 2 minutes upon contact between the

solid and aqueous environment resulting in a release of the surface stabilized drug particles into the aqueous environment as a suspension and after contact between the solid and the aqueous environment, the resulting suspension comprises no more than about 20% by weight of aggregated or agglomerated primary particles.

Claims 1-22 of Parikh III do not teach or suggest a process for the preparation of a rapidly disintegrating solid dosage form. Specifically, Parikh III does not teach or suggest a process for the preparation of rapidly disintegrating solid dosage form comprising a phospholipid in the aqueous suspension that ranges from about 0.1% w/w to about 90% w/w, with a mean volume weighted particle size of the water-insoluble or poorly water-soluble drug particles in the suspension between 0.05 and 10 micrometers. Moreover, claims 1-22 of Parikh III do not teach or suggest a process for the preparation of rapidly disintegrating a solid dosage form with at least two rapidly dispersible matrix-forming agents being present in an amount of between 0.1% w/w and 90% w/w of the aqueous suspension wherein upon reconstitution in an aqueous environment, the suspension has no more than about 20% by weight of particle aggregation or agglomeration compared with the amount of aggregation or agglomeration of particles comprising a pre-dried suspension. Furthermore, claims 1-22 Parikh II does not encompass a process for the preparation of rapidly disintegrating solid dosage form with a support matrix that dissolves or disperses in a rapid disintegration time of less than 2 minutes upon contact between the solid and aqueous environment resulting in a release of the surface stabilized drug particles into the aqueous environment as a suspension.

For the above reasons, Applicants submit that claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 are not obvious over the teachings of claims 1-22 of Parikh III and respectfully request that this rejection be withdrawn.

Claims 50-52, 54, 56-75, 77, 79-95, 97-104 and 108-131 remain provisionally rejected under the obviousness-type double patenting over claims 1, 2, 4-25, 45-47, 52-53, 55-56, 65 and 101-119 of co-pending application U.S. Serial No. 10/260,788. Applicants note that this is a provisional double patenting rejection for which the M.P.E.P. at § 1504.06 Double Patenting provides as follows:

If a provisional double patenting rejection (of any type) is the only rejection remaining in two conflicting applications, the examiner should withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the provisional double patenting rejection in the other application which rejection will be converted into a double patenting rejection when the first application issues as a patent. If more than two applications conflict with each other and one is allowed, the remaining applications should be cross rejected against the others as well as the allowed application. For this type of rejection to be appropriate, there must be either at least one inventor in common, or a common assignee. If the claims in copending design applications or a design patent and design applications have a common assignee but different inventive entities, rejections under 35 U.S.C. 102(e), (f) and (g)/103(a) must be considered in addition to the double patenting rejection. See MPEP Section 804, Section 2136, Section 2137 and Section 2138.

Accordingly, should the Examiner find the present claims allowable in view of the above amendments and/or arguments, Applicant respectfully request withdrawal of this provisional rejection.

**Conclusion**

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below. The Commissioner is hereby authorized to charge payment of any fees that may be required, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 28069-546.

Respectfully submitted,

  
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